European medical device competent authorities statement on reform of the EU regulatory framework for medical devices.

July 2025

Statement Summary

Improving coordination and governance of the regulatory system for medical devices at the EU level is crucial to address fragmentation and enhance harmonisation and effective application in practice. This will help to ensure the protection and enhancement of the health of EU citizens. To achieve this, a more centralised and cohesive structure is needed to support certain regulatory activities, and to provide predictability, clarity, consistency, and harmonisation of the application of requirements. Furthermore, investment in sufficient resources and a sustainable funding model is essential to ensure a well-functioning regulatory system, with costs that are fair, clear, and value-driven. This includes strategic investments to improve coordination and governance, which will lead to long-term savings and benefits for all stakeholders. Ultimately this will deliver a simple, clear, and well-functioning regulatory system.

Introduction

The medical device competent authorities from Austria, Belgium, Croatia, Denmark, Estonia, Finland, France, Germany, Hungary, Ireland, Liechtenstein, Norway, Poland, Portugal, Slovenia, Spain and Sweden met in Utrecht, together with the EU Commission participating as an observer, and hosted by the Dutch Ministry for Health, Welfare and Sport. The purpose was to discuss the need to reform and develop further supports to allow the EU regulatory framework described under the current EU Medical Device Regulations[1] to work in a more consistent, harmonised and effective way in practice.

Background and context

Authorities discussed the governance and coordination of the EU regulatory system and to explore opportunities for centralisation of certain activities to support the practical application of the existing medical device regulations in Europe.

In a July 2024 statement, the authorities affirmed their commitment to the practical application of the EU Regulations to allow for a predictable, reliable, secure and efficient regulatory system, to advance and protect the health of people across Europe. The authorities called for a careful examination at EU level of the resources, capability and structural needs to deliver an efficient, effective, proportionate and value-driven regulatory system.

[1] EU Medical Device Regulation (EU 2017/745 – MDR). EU *In-vitro* diagnostics Regulation (EU 2017/746 – IVDR)

Key conclusions and recommendations

The authorities stand by these commitments while recognising that EU discussions and the regulatory environment have evolved since July 2024. Today they concluded that:

1. Improving coordination and governance of the regulatory system at EU level is essential to address fragmentation and to improve harmonisation. To ensure success of the system, this governance model needs to be scientifically founded and have a strong scientific, technical and administrative secretariat support.
2. A more centralised and cohesive structure is needed to support certain regulatory activities and to help provide predictability, clarity, consistency and harmonisation in the application of the requirements.
3. Proportionate, patient-centred and adaptive regulatory approaches are needed to allow timely access for patients and health systems to medical technologies while also supporting the ongoing safety of medical devices in Europe. While reliant upon coordination and a clear governance model, the delivery of these goals could also benefit from a more centralised approach.
4. Simplification, clarification and removal of unnecessary burden of the Regulations is needed to improve efficiency and predictability, to provide a stable sector, and to promote EU competitiveness. Appropriate supports are needed to ensure equitable access to the regulatory system for all stakeholders, including micro-enterprises. Achieving this in a coherent manner is reliant on effective governance founded on regulatory science and international best practices.
5. Investment in the provision of sufficient and capable resources at both a European and national level, facilitated by a sustainable funding model, is key. Costs associated with regulatory compliance and processes should be fair, clear, value-driven and justifiable. Strategic investments in the regulatory system will lead to long-term savings and a simple, clear and well-functioning regulatory system for the benefit of patients and the regulated sector.

Next steps and actions

The authorities recognised the significant work being undertaken by the European Commission to deliver short term measures, simplify the system and complete a targeted evaluation of the regulatory framework. The authorities called on the need for a detailed plan and resource assessment to improve the governance model and to examine the potential ways that operational coordination and centralisation could benefit the system. This will require appropriate legislative supports, over and above what is described within the current Regulations.

Regarding the provision of appropriate technical, scientific and regulatory support, the existing expertise at both national authority and notified body levels, was acknowledged. The authorities recognise the support that a central agency could provide. This could be an important step in reinforcing a scientific foundation for the regulatory system at EU level while also providing for a scientific secretariat, a stable knowledge base and access where relevant to external expertise (such as the expert panels described in the Regulations).

The authorities also discussed practical aspects relating to a selection of activities which could be considered from a more centralised and scientific approach including; cooperation between competent authorities on operational issues (e.g. vigilance assessments), designation and oversight of notified bodies, provision of scientific and regulatory advisory services to innovators and manufacturers; implementation of adaptive pathways to apply proportionate approaches for specific product categories (e.g. breakthrough technologies); and, to provide answers, information and guidance to specific questions to support consistent, harmonised and predictable application of the requirements.

Reflecting on the discussions, the authorities agreed that there is an urgent need, and also a clear momentum, to address the topic of governance and centralisation. They acknowledged the evolution of views and discussion on this topic since the July 2024 workshop both between authorities and in the stated position of relevant stakeholders and the EU Institutions.

The authorities were clear that additional supports and legislative provisions are required to achieve effective application of the EU Regulations, going beyond adjustment, simplification and clarification of the existing Regulations.

The authorities reaffirmed their strong commitment to continue to support the work of the European Commission in addressing short and medium term priorities while calling on the Commission to fully assess, address and develop the provisions relating to governance and coordination and the role of centralisation in the future regulatory system development.

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